

- 11 -

Claims

- 1) A process for the preparation of gabapentin comprising the passage of a salt of the same through an ionic exchange resin of strong cationic type, the elution of the gabapentin which  
5 has fixed onto the column and the crystallization from organic solvent, characterized in that the regeneration of the ionic exchange resin of strong cationic type is carried out:
- a. by partially regenerating the resin through a beater constituted by an aqueous solution of inorganic acid in a quantity equal to a percentage of resin moles comprised between 50 and 90%;
  - 10 b. by adding demineralized water in a quantity sufficient to separate the beater from the solution of a gabapentin salt of item c.;
  - c. by adding a solution of gabapentin salt and by completing the resin regeneration through the acid released by fixing the gabapentin salt to the resin itself;
  - d. by eluting the gabapentin which has fixed to the resin by using a base.
- 15 2) A process according to claim 1 wherein the partial regeneration of the ionic exchange resin of strong cationic type is carried out by using an aqueous solution of inorganic acid in a quantity equal to a percentage of the resin moles around 70-80%.
- 3) A process according to claim 1 wherein the partial regeneration is carried out by using an aqueous solution of an inorganic acid chosen among hydrochloric, nitric and sulfuric acid.
- 20 4) A process according to claim 3 wherein the partial regeneration is carried out with an aqueous solution of hydrochloric acid.
- 5) A process according to claim 4 wherein the aqueous solution of hydrochloric acid has a concentration comprised between 5 and 10%.
- 6) A process according to claim 5 wherein the aqueous solution of hydrochloric acid has a  
25 concentration around 6%.
- 7) A process according to claim 1 wherein the partial regeneration of the ionic exchange resin of strong cationic type is carried out by using an aqueous solution of inorganic acid corresponding to the anion of the gabapentin addition salt.
- 8) A process according to claim 1 wherein the elution of the gabapentin which has fixed to  
30 the resin is carried out by using an aqueous solution of ammonia.

- 12 -

- 9) A process according to claim 1 wherein the elution of the gabapentin which has fixed to the resin is carried out by using an aqueous solution of ammonia and alkaline hydroxide.
- 10) A process according to claim 9 wherein the alkaline hydroxide is NaOH.
- 5 11) A process according to claim 10 wherein the aqueous solution of  $\text{NH}_3$  and NaOH is obtained by mixing an aqueous solution of 3-4% ammonia and an aqueous solution of 7-8% sodium hydroxide.
- 12) A process according to claim 11 wherein the molar ratio between ammonia and sodium hydroxide is comprised between 1:1 and 1:2.
- 10 13) A regeneration process of a strong cationic exchange resin used in the purification of a gabapentin salt comprising:
- a. the partial regeneration of the resin through a beater constituted by an aqueous solution of inorganic acid in a quantity equal to a percentage of resin moles comprised between 50 and 90%;
- 15 b. the addition of demineralized water in a quantity sufficient to separate the beater from the solution of a gabapentin salt of item c.;
- c. the addition of a solution of a gabapentin salt and the completion of the resin regeneration through the acid released by fixing the gabapentin salt to the resin itself.
- 14) A process according to claim 13 wherein the partial regeneration of the ionic exchange  
20 resin of strong cationic type is carried out by using an aqueous solution of inorganic acid in a quantity equal to a percentage of resin moles around 70-80%.
- 15) A process according to claim 13, wherein the partial regeneration is carried out by using an aqueous solution of an inorganic acid chosen among hydrochloric, nitric and sulfuric acid.
- 16) A process according to claim 15, wherein the regeneration is carried out with an aqueous  
25 solution of hydrochloric acid.
- 17) A process according to claim 16, wherein the aqueous solution of hydrochloric acid has a concentration comprised between 5 and 10%.
- 18) A process according to claim 17, wherein the aqueous solution of hydrochloric acid has a concentration around 6%.
- 30 19) A process for the preparation of gabapentin comprising the passage from gabapentin

- 13 -

hydrochloride through an ionic exchange resin of strong cationic type, the elution of the gabapentin which has fixed onto the column, the concentration and the crystallization from organic solvent, characterized in that the regeneration of the ionic exchange resin of strong

5 cationic type is carried out:

a. by partially regenerating the resin through a beater constituted by an aqueous solution of hydrochloric acid in a quantity equal to a percentage of resin moles comprised between 50 and 90%;

10 b. by adding demineralized water in a quantity sufficient to separate the beater from the solution of a gabapentin hydrochloride of item c.;

c. by adding a solution of gabapentin hydrochloride and by completing the resin regeneration through the hydrochloric acid released by fixing the gabapentin hydrochloride to the resin itself;

d. by eluting the gabapentin which has fixed to the resin by using a base.

15 20) A process according to claim 19, wherein the partial regeneration of the ionic exchange resin of strong cationic type is carried out by using an aqueous solution of hydrochloric acid in a quantity equal to a percentage of the resin moles around 70-80%.

21) A process according to claim 19, wherein the elution of the gabapentin which has fixed to the resin is carried out by using an ammonia aqueous solution.

20 22) A process according to claim 19, wherein the elution of the gabapentin which has fixed to the resin is carried out by using an aqueous solution of ammonia and alkaline hydroxide.

23) A process according to claim 19, wherein the aqueous solution of hydrochloric acid has a concentration comprised between 5 and 10%.

25 24) A process according to claim 23, wherein the aqueous solution of hydrochloric acid has a concentration around 6%.